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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,450	11/27/2006	Kristofer Olofsson	1090-127	8515

23117 7590 01/29/2009

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,450	OLOFSSON ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12/10/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *4-13,16,33 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,14,15,17-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06/2007, 10/03/2006, and 8/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-37 are currently pending. Claims 33 and 37 are withdrawn. Additionally, claims 4-13 and 16 which are drawn to a non-elected species are withdrawn. Accordingly, claims 1-3, 14-15, 17-32 and 34-36 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

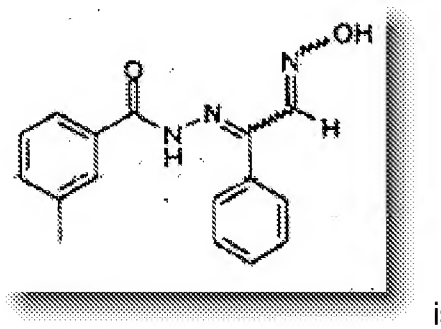
Election/Restrictions

2. Applicant's election of Group I in the reply filed on 12/10/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 33 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without specifying** traverse in the reply filed on 12/10/2008.

5. Applicant's election of the following compound species



is also acknowledged. The elected specie reads upon

claims 1-3, 14-15, 17-32 and 34-36. Claims 4-13 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without specifying** traverse in the reply filed on 12/10/2008.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 14-15, 17-32 and 34-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112 second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 1-3, 14-15, 17-32 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention**.

9. Claims 1-3, 14-15, 17-32 and 34-36 are rejected under 35 U.S.C. 112 second paragraph for the following reasons: instant claims 1-3, 14-15, 17-32 and 34-36 provide

for the "use of a compound of formula I" or compounds, products or kits comprising a compound of formula I "as defined in claim 1". However, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

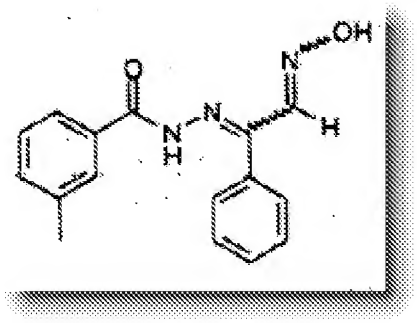
Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

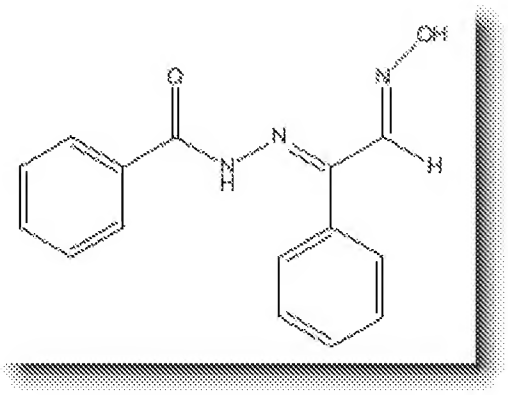
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 1-3, 14-15, 17-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Misra et al* (J Indian Chem Society 39:763-764, 1962 - cited by Applicant, Specification Page 5, Lines 3-4) - as evidenced by the *Encyclopedia Britannica* - and *Patani et al* (Chem Rev 96:3147-3176, 1996).**

13. Instant claim 1 is drawn to a compound of formula I wherein Applicant has specifically elected the following compound:  , which reads on claims 1-3, 14-15, 17-30. Furthermore, as disclosed by Applicant, the compounds are allegedly useful "in the treatment of inflammatory diseases and of inflammation generally" (Specification Page 1, Lines 9-10).

14. *Misra et al* teach antituberculosis compounds (Title). As evidenced by the Encyclopedia Britannica (accessed online January 11, 2009 at http://www.britannica.com, "[c]hronic inflammation can be brought about by infectious organisms that are able to resist host defenses and persist in tissues for an extended period of time. These organisms include *Mycobacterium tuberculosis* (the causative agent of tuberculosis)" (Paragraph 2). Accordingly, the compounds taught by *Misra et al* are functionally similar to the instant compounds since (as evidenced by the Encyclopedia Britannica) compounds that treat tuberculosis are, by definition, compounds which treat an inflammatory disease. Moreover, as evidenced by the attached CAPLUS report (Accession Number 1963:415491), *Mirsa et al* teach the

following compound:  (RN 58644-42-1). As such, the **only** difference between the prior art and the instant compound is that *Misra et al* teach a compound wherein phenyl is unsubstituted, whereas the instant claims are drawn to a compound wherein phenyl is substituted at the 3 position with methyl. Accordingly, *Misra et al* teach compounds which are both functionally and structurally similar. As stated by MPEP 2144.09:

> A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979).

. Furthermore:

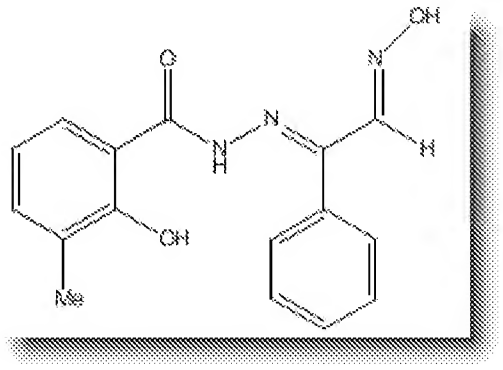
> Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

In the instant case, the claimed compound specie is *prima facie* obvious over the prior art as follows:

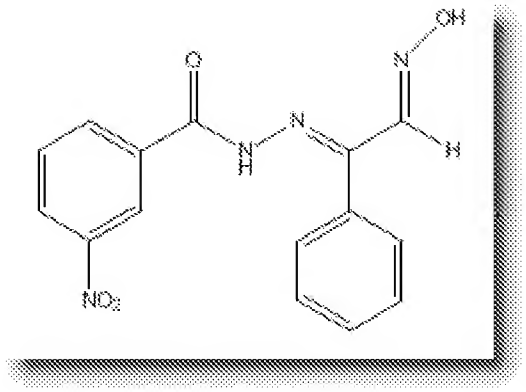
15. **FIRST**, as discussed above, the instant compound specie is structurally and functionally similar to the compound taught by *Misra et al*, differing only in the addition of a single methyl group at the 3 position of the phenyl ring.

16. **SECOND**, as disclosed by *Patani et al*, "[t]he substitution of hydrogen by fluorine is one of the more commonly employed monovalent isosteric replacements" (Page 3149, Column 1) and methyl is a well known isostere of fluorine (Page 3148, Column 2, Table 2).

17. **And THIRD**, *Misra et al* teach structurally and functionally related compounds wherein the phenyl ring is substituted at the 3 position, for example:



(RN 7021-32-1) and



(RN 93721-80-3).

18. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include methyl in the 3 position of the phenyl ring of the compound taught by *Misra et al* to arrive at the compound specie of the instant claims. As stated in *Aventis Pharma Deutschland GmbH v. Lupin, LTD* No. 06-1530 (Fed. Cir. 2007), "[i]n the chemical arts, we have long held that 'structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.' *Takeda Chem. Indus., Ltd. V. Alphapharm Pty., Ltd.*, No 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In*

re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc)); see also *In re Papesch*, 315 F.2d 381 (CCPA 1963). The 'reason or motivation' need not be an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a "sufficiently close relationship... to create an expectation," in light of the totality of the prior art, that the new compound will have "similar properties" to the old. *Dillon*, 919 F.2d at 629." As discussed above, the prior art compounds taught by *Misra et al* are structurally and functionally similar to the instantly claimed compound specie. Furthermore, *Patani et al* provide the reason and motivation to modify the compounds as taught by *Misra et al* to arrive at the instantly claimed compound specie. In particular, given the disclosure of *Misra et al* that structurally and functionally related compounds can be specifically modified at the 3 position of the phenyl ring, the skilled artisan would have found it obvious to use the teaching of *Patani et al* to modify the compounds of *Misra et al* specifically at the 3 position of the phenyl ring, and would have reasonably expected such compounds to possess similar properties given their close structural relationship to the prior art. As such, claims 1-4, 14-15, 17-329 are rejected as *prima facie* obvious.

19. Instant claims 30-32 are drawn to the compound of claim 1 for the inhibition of the activity of 15-lipoxygenase (claim 30) and the treatment of related diseases (claims 31-32). Applicant is advised that use limitations within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art

structure is capable of performing the intended use, then it meets the claim. In the instant case, the use limitations of claims 30-32 are not afforded any patentable weight because there is nothing that would exclude the prior art compound from performing the recited functions. Accordingly, claims 30-32 fail to introduce any further limitations and are thus rejected for the reasons stated above as applied to instant claim 1.

20. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Misra et al* (J Indian Chem Society 39:763-764, 1962 - cited by Applicant, Specification Page 5, Lines 3-4) - as evidenced by the *Encyclopedia Britannica* - and *Patani et al* (Chem Rev 96:3147-3176, 1996) as applied to claim 1 above, in further view of *Barrow et al* (WO 2000/10533) as evidenced by *Jain et al* (Dermatology Online Journal 8(2):2, 2002).

21. Instant claims 34-36 are drawn to a combination product (claim 34) a pharmaceutical formulation (claim 35) and a kit (claim 36) which combine the compound of formula I with another therapeutic agent useful in the treatment of inflammation, and a pharmaceutically acceptable adjuvant, diluent or carrier (in various combinations). As discussed above, *Misra et al* teach compounds that are useful in the treatment of tuberculosis. Accordingly, the compounds taught by *Misra et al* are, by definition, useful in the treatment of chronic inflammation. As stated in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ

1069, 1072 (CCPA 1980). Furthermore, *Barrow et al* specifically teach “compositions and methods for treating intracellular infections” (Title), specifically tuberculosis (Page 8, Paragraph 1) using drugs such as "tetracyclines" (Page 8, Paragraph 3) and “erythromycin” (Page 8, Paragraph *3) which, as evidenced by *Jain et al*, are anti-inflammatory agents (Title). Additionally, *Barrow et al* disclose that “[i[n most known treatment regimens, tuberculosis is treated with two or more drugs” (Page 9, Paragraph 1) and state that “a combination of... drugs could be administered, in the same or different microspheres" (Page 9, Paragraph 1). *Barrow et al* also disclose that the compositions "can be administered with a pharmaceutically acceptable carrier and, in addition, may include other medicinal agents, pharmaceutical agents, carriers, adjuvants, diluents, etc" (Page 10, Paragraph 1) using “two routes of injection, intravenous and subcutaneous” (Page 10, Paragraph 3). And *Barrow et al* also teach kits (Page 2, Paragraph 4). As such, *Barrow et al* teach functionally related compositions in combinations, formulations and kits which can comprise anti-inflammatory agents and diluents, carriers, or adjuvants and which can be provided in a form suitable for administration in conjunction with the other. Accordingly, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to formulate combinations comprising the compound specie and another anti-inflammatory compound either as a combination product (as recited by instant claim 34), a pharmaceutical formulation (as recited by instant claim 35) or a kit (as recited by instant claim 36).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614